K110221

510(k) Summary for Eye-Cept® Sterile Saline Solution

NOV - 1 2011

A. Sponsor

Optics Laboratory, Inc.
9480 Telstar Ave Ste 3
El Monte, CA 91731-2988

B. Contact

Patricia Chiu, CEO
Optics Laboratory, Inc.
Phone: 1-626-350-1926
Fax: 1-626-350-1906
Summary prepared October 2011

C. Device Name

Trade Name:

Eye-Cept® Sterile Saline Solution

Common Name:

Contact Lens Saline Solution

Classification Name:

Soft contact lens care products (21 CFR 886.5928, Product Code LPN)

D. Predicate Device(s):

Cachet Saline Solution - K093367
Alcon (formerly Cooper) Unisol® Saline Solution – P790011

E. Device Description:

Eye-Cept® Sterile Saline Solution is provided in single use, carry-on size bottles that are preservative free. It rinses loose debris and cleaning solution off soft (*hydrophilic*) contact lenses. It is only for use to rinse and wet soft contact lenses (a) after cleaning before disinfection and (b) after disinfection before using. It is not a disinfectant nor should it be used as eye drops. It is a clear solution and should not be used, if cloudy or discolored. The individual 10 ml bottle should not be kept once used; it should be discarded after opening. It should not be used after its labeled expiry date.

F. Intended Use:

Eye-Cept® Sterile Saline Solution is intended for use rinsing soft (*hydrophilic*) contact lens after cleaning and wetting before use after disinfection.

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G. Technological Characteristics:

Eye-Cept® Sterile Saline Solution is a sterile, preservative-free, aqueous solution of sodium chloride, boric acid, and sodium borate provided in single dose 10ml bottles. The sterile saline solution has pH of 7.2-7.8 and tonicity of 290 – 320 mOsm/kg.

Device Characteristic	Optics Laboratory Eye-Cept® Sterile Saline Solution	K093367	P790011
For hydrophilic contact lenses	Y	Y	Y
For rinsing and thermal disinfection	N	N	Y
Preservative-Free	Y	Y	Y
Sterile	Y	Y	Y
Aqueous solution of NaCl & Borates	Y	Y	Y
pH balanced	Y	Y	Y
Multi-Dose Container	N	N	Y
Polyethylene Container	Y	Y	Y
Propellants	N	N	N

H. Substantial Equivalence:

A series of studies were completed to demonstrate the substantial equivalence of Eye-Cept® Sterile Saline Solution to the predicate devices. All testing was conducted in accordance with and in conformance to applicable device regulations and guidance. Results of all testing demonstrate the solution is non-toxic, is comparable to other currently marketed soft contact lens solutions, and is substantially equivalent to legally marketed predicates. These studies followed the "Testing Matrix for Saline Solutions" of the "Guidance for Industry – Premarket Notification (510k) Guidance Document for Contact Lens Care Products, issued May 1, 1997" and included:

1. *in vitro* cytotoxicity of both the saline solution and the polyethylene container
2. acute ocular irritation
3. antibacterial effectiveness

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" a direct comparison of key characteristics demonstrates that the proposed saline solution is substantially equivalent to the predicate device in terms of intended use, technological characteristics, and performance characteristics. The proposed Optics Laboratory Eye-Cept® Sterile Saline Solution is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Optics Laboratory, Inc.
c/o Dr. George Samaras
Official Correspondent
Samaras & Associates, Inc.
7755 Soda Creek Road
Pueblo County, CO 81005-9763

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Re: K110221
Trade/Device Name: Eye-Cept® Sterile Saline Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: October 5, 2011
Received: October 14, 2011

Dear Dr. Samaras:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

Indications for Use:

510(k) Number (if known):

K 110221

Device Name:

Eye-Cept® Sterile Saline Solution

Indications for Use:

Eye-Cept® Sterile Saline Solution is indicated only for rinsing soft contact lenses after cleaning and for wetting soft contact lenses after disinfection before use.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marc Robbay

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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